

TRANSLATION**PATENT COOPERATION TREATY****PCT****INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 51962 WO	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/EP2004/052109	International filing date (<i>day/month/year</i>) 09.09.2004	Priority date (<i>day/month/year</i>) 25.09.2003
International Patent Classification (IPC) or national classification and IPC G01N21/82, G01N21/59, G01N33/543		
Applicant ODEFEY, Constantin		

1.	This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2.	This REPORT consists of a total of <u>8</u> sheets, including this cover sheet.
3.	This report is also accompanied by ANNEXES, comprising: a. <input checked="" type="checkbox"/> (<i>sent to the applicant and to the International Bureau</i>) a total of <u>4</u> sheets, as follows: <input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. b. <input type="checkbox"/> (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4.	This report contains indications relating to the following items: <input checked="" type="checkbox"/> Box No. I Basis of the report <input type="checkbox"/> Box No. II Priority <input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

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Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages 1-4, 6-23 as originally filed/furnished
- pages* 5 received by this Authority on 24.03.2005 with letter of 23.03.2005
- pages* _____ received by this Authority on _____
- ☒ the claims:
- nos. _____ as originally filed/furnished
- nos.* _____ as amended (together with any statement) under Article 19
- nos.* 1-11 received by this Authority on 24.03.2005 with letter of 23.03.2005
- nos.* _____ received by this Authority on _____
- ☒ the drawings:
- sheets 1/3-3/3 as originally filed/furnished
- sheets* _____ received by this Authority on _____
- sheets* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1. Statement			
Novelty (N)	Claims	<u>1-11</u>	YES
	Claims		NO
Inventive step (IS)	Claims	<u>1-11</u>	YES
	Claims		NO
Industrial applicability (IA)	Claims	<u>1-11</u>	YES
	Claims		NO
2. Citations and explanations (Rule 70.7)			
<p>1. The amendment made in claim 2 does not introduce any substantive matter that goes beyond the disclosure of the application as filed, and therefore it meets the requirements of PCT Article 34(2) (b).</p>			
<p>2. Novelty</p> <p>Claims 1-11 are novel within the meaning of PCT Article 33(2), since the prior art contains no method in which an agglutination reaction is demonstrated by detecting a signal using an extinction measurement at the light-dark border of a cone of light.</p> <p>Furthermore, the prior art discloses no such kits or computer program codes that make possible such a measurement.</p>			
<p>3. Inventive step</p>			
<p>3.1 Claims 1-8 meet the requirements of PCT Article 33(3). Claim 1 relates to a method</p>			

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	<p>for detecting small quantities of particles in a solution, wherein the formation of particle precipitates through antigen-antibody reactions is determined by an extinction measurement at the light-dark border of a cone of light generated by a laser beam.</p> <p>Methods in which particle aggregation through antigen-antibody binding are used to measure an analyte are sufficiently well-known in the prior art (cf. US-5 534 441 (D1), and as an additional example, US-5 100 805). Optical methods for detecting the aggregates thereby formed are likewise known and involve light scattering and transmission measurements (cf. D1).</p> <p>The subject matter of claim 1 differs from these methods in that the detection method used is an extinction measurement carried out in the sample at the light-dark border of the laser-generated cone of light.</p> <p>Therefore, the problem to be solved by the present invention can be regarded as that of providing a sensitive alternative to the methods described in the prior art.</p> <p>Methods are known wherein the size of a particle in solution is determined by the diffusion time in a small cone of light.</p>

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	<p>Fluorescence correlation spectroscopy is cited here as an example (cf. D1: EIGEN M ET AL: "SORTING SINGLE MOLECULES: APPLICATION TO DIAGNOSTICS AND EVOLUTIONARY BIOTECHNOLOGY" PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF USA, NATIONAL ACADEMY OF SCIENCE. WASHINGTON, US, Vol. 91, June 1994 (1994-06), pages 5740-5747 (D3)).</p> <p>The prior art neither discloses nor renders obvious, however, the measurement of the extinction change in a sample when particles pass through the light-dark border of a cone of light, in order to arrive at a size measurement and therefore at a size distribution of the particles or their aggregates. Therefore, this also neither discloses nor renders obvious the fact that said detection techniques provide an extremely sensitive measuring method that is easy to carry out.</p> <p>Therefore, claim 1 and claims 2-8, which are dependent thereon, are regarded as inventive within the meaning of PCT Article 33(3).</p> <p>3.2 Claims 9 and 10 relate to a computer program containing codes for carrying out the method according to claims 1-8 and are therefore likewise novel and inventive within the meaning of PCT Article 33(2) and (3).</p>

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	<p data-bbox="396 359 1377 831">3.3 Claim 11 is regarded as inventive within the meaning of PCT Article 33(3). The claim relates to a kit containing a device having a laser, a measuring chamber, and a photo receiver, the photo receiver being configured to carry out an extinction measurement at the light-dark border of the cone of light, which is produced when the light generated by the laser passes through the particles in a measuring chamber containing a fluid.</p> <p data-bbox="513 903 1373 1178">According to the description on page 3, lines 8-11, this measurement is achieved through a slightly offset arrangement of the laser and the photo receiver, the effect of which is that the laser beam passes closely by the photo receiver.</p> <p data-bbox="513 1249 1373 1377">Arrangements for measuring agglutination reactions through extinction measurements are known from the prior art.</p> <p data-bbox="513 1449 1373 1919">US-5 534 441 (D1) discloses a device for detecting immunological agglutination reactions of functionalized particles, comprising a measuring chamber, a laser light source and a photo multiplier that measures the light passing through the sample (see the passage cited in the search report). D1 does not, however, disclose or render obvious an offset arrangement of the laser and the photo receiver.</p>

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Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
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Therefore claim 11 meets the requirements of
PCT Article 33(3).

4. Claims 1-11 are industrially applicable and
therefore meet the requirements of PCT
Article 33(4).

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claim 1 does not appear to meet the requirements of PCT Article 6, because the technical features necessary for carrying out the method according to the claim are not clearly defined.

Claim 1 relates to the determination of the size and number of particles or their aggregates in the sample by an extinction measurement at the light-dark border of a cone of light.

Aside from the measurement of the extinction and the signal strength of the light detected thereby, claim 1 contains nothing that indicates how the number and size of the particles is actually determined.

The description, for example, indicates that said parameters are determined from the time required for the transition through the cone of light (page 11, second paragraph).

Since claim 1 does not contain the technical features necessary for the actual determination of the above-mentioned measured values, it does not meet the requirements of PCT Article 6.